REMARKS

In response to the Office Action mailed February 23, 2006 Applicants submit the following amendments and remarks. Claims 1, 2, 18, 41, 44, and 49-52 are pending in the instant application. Claims 3-40 have been cancelled by way of this amendment. Claims 1, 2, 41, 44, and 51 have been amended by way of this amendment. In particular, Claims 1 and 2 have been amended to clarify the claim scope and to remove references to non-elected subject matter. Claims 41 and 44 have been amended to depend from Claim 1. Claim 51 has been amended to add a sequence identifier. No new matter has been added by way of this amendment. Claims 1, 2, 18, 41, 44, and 49-52 are presented for further examination.

Applicants respectfully submit that the amendments above along with the remarks below place the pending product claims in condition for allowance. Applicants note that the Examiner previously required restriction between product and process claims. Because Claim 1, drawn to a novel product, is believed to be in condition for allowance, Applicants request rejoinder of withdrawn process Claims 42-43 and 45-48, which are drawn to process of using the claimed product and include all of the limitations of Claim 1, in accordance with the provisions of M.P.E.P. § 821.04. Applicants have amended withdrawn Claims 42, 45, and 47 by way of this amendment. Specifically, Claim 42 has been amended to clarify the claimed method and Claims 42, 45 and 47 have been amended to include all of the limitations of Claim 1. In addition, Applicants have added new Claim 53 drawn to a method for manufacturing the antibody of Claim 1. Support for new Claim 53 can be found throughout the specification and claims as originally filed, for example, at paragraphs [0114] and [0115] and the Examples. Thus, no new matter has been added by way of this amendment. Applicants respectfully request entry of this amendment prior to rejoinder and examination of these claims.

Informalities

The Examiner objected to Claim 51 for listing an amino acid sequence without a corresponding sequence identifier. As requested by the Examiner, the amino acid sequence in Claim 51 has been assigned SEQ ID NO: 150, which has been incorporated into the claim language. A Substitute Sequence Listing and Sequence Submission Statement are filed herewith.

Claim Objections

The Examiner objected to Claims 1 and 2 because the claims consist of non-elected inventions. In response to this objection, Applicants have amended these claims to remove references to the non-elected sequences. Withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 49, 50 and 51 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification as such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserts that it is not clear that the monoclonal antibodies 3.11.1 or 3.11.2 are known and publicly available or can be reproducibly isolated from nature without undue experimentation. Applicants interpret this rejection to apply to Claims 49, 50, and **52**, as Claim 51 does not recite the monoclonal antibodies 3.11.1 or 3.11.2.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' . . . . Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

Regarding deposit of biological materials, M.P.E.P. § 2404.02 states that Applicants may show that a deposit is not necessary even though specific biological materials are required to practice the invention if those biological materials can be made or isolated without undue experimentation. In particular, courts have held that "no deposit is required where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test." M.P.E.P. § 2404.02 (citing *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977); Ex Parte Hata, 6 USPQ2d 1652 (Bd. Pat. App. & Int. 1987)).

Applicants respectfully submit that deposit of monoclonal antibodies 3.11.1 and 3.11.2 is not necessary because these antibodies can be obtained from publicly available material with only routine experimentation. In particular, Applicants provide both nucleic acid and amino acid sequences for the heavy and light chains of monoclonal antibody 3.11.1 in the specification as

filed at SEQ ID NOS: 61-64. See Table 1, page 15 and Figure 9A of the specification and SEQ ID NOS: 61-64 of the Sequence Listing. Figure 9A further indicates the specific amino acid sequences of the CDR regions of monoclonal antibody 3.11.1. In addition, Applicants provide the specific gene families encoding the immunoglobulin variable regions of the heavy and light chains of monoclonal antibody 3.11.1. See Table 11, page 71. Monoclonal antibodies 3.11.1 and 3.11.2 are identical clones. Thus, Applicants respectfully submit that a person of ordinary skill in the antibody art having the above-identified information could obtain monoclonal antibodies 3.11.1 or 3.11.2 using publicly available material and conventional molecular biology and immunology techniques. Because monoclonal antibodies 3.11.1 and 3.11.2 can be made or isolated without undue experimentation given the disclosure provided in the instant specification, Applicants respectfully submit that deposit of these antibodies is not required.

In light of the foregoing, Claims 49, 50, and 52 are fully enabled by the specification as required by 35 U.S.C. § 112, first paragraph. Applicants respectfully request that the rejection under this section be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: June 23, 2006

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